

REMARKS

I. PRELIMINARY REMARKS

Claims 1, 5, 6, 9-13, 15, 17-19, 21, 24-27 and 33 have been amended.¹ Claims 2, 29-32, 34 and 35 have been canceled. Claims 36-48 have been added. Claims 1, 3-28, 33 and 36-48 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

Applicant filed Information Disclosure Statements ("IDSs") on April 26, 2002 and June 13, 2002. Copies of the IDSs, including the PTO form 1449s and date stamped postcard receipts, are attached hereto as Exhibit 1. The Office Action does not include any indication that the IDSs have been considered. Accordingly, applicant hereby requests that the Examiner consider the IDSs, initial the PTO form 1449s and return them to applicant with the next Office Action.

II. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 19-24 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully submits that the rejection under 35 U.S.C. § 112 has been obviated by the amendment above. More specifically, the minor typographical error in claim 19 has been corrected. The rejection under 35 U.S.C. § 112 should, therefore, be withdrawn.

¹ Applicant notes that the claims 5, 6, 9-13, 17, 18, 21 and 24-27 have been amended solely in order to bring the language therein into conformance with that now presented in independent claims 1 and 15.

III. REJECTIONS OF CLAIMS 1-28 UNDER 35 U.S.C. §§ 102 AND/OR 103

A. The Rejections

Claims 1-3, 15 and 16 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,255,678 to Deslauriers (the Deslauriers '678 patent).

Claims 1, 2, 5-11, 15, 17-20 and 25 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,961,513 to Swanson (the Swanson '513 patent). Claims 3, 4 and 16 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Swanson '513 patent and U.S. Patent No. 5,392,923 to Lundquist (the Lundquist '923 patent). Claims 21-24 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Swanson '513 patent and U.S. Patent No. 5,496,311 to Abele (the Abele '311 patent).

Claims 1-5, 11-17 and 25-28 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of U.S. Patent No. 5,707,349 to Edwards (the Edwards '349 patent) and U.S. Patent No. 5,800,484 to Gough (the Gough '484 patent).

The rejections under 35 U.S.C. §§ 102 and 103 are respectfully traversed with respect to the claims as amended above. Reconsideration thereof is respectfully requested.

B. The Claimed Combinations

Independent claims 1 and 15 call for respective combinations of elements comprising "a relatively short, relatively stiff shaft" and "an inflatable, energy transmitting lesion formation element associated with the distal portion of the shaft that allows substantially no liquid perfusion therethrough."

C. Rejection Based on the Deslauriers '678 Patent

The Deslauriers '678 patent, which is directed mapping electrode balloons, fails to teach or suggest each and every element in the respective combinations defined by independent claims 1 and 15. For example, none of the Deslauriers balloons are an "inflatable, **energy transmitting lesion formation element**," as called for in the respective combinations defined by independent claims 1 and 15. As the Deslauriers '678 patent fails to teach or suggest each and every element of the respective combinations recited in independent claims 1 and 15, applicant respectfully submits that claims 1-3, 15 and 16 are patentable thereover and that the rejection under 35 U.S.C. § 102 should be withdrawn.

D. Rejections Based on the Swanson '513 Patent Alone and in Combination With Other Patents

The Swanson '513 patent, which discloses a variety of catheter-based tissue heating devices, fails to teach or suggest each and every element in the respective combinations defined by independent claims 1 and 15. For example, the Swanson catheter tube 12 is configured to move through a main vein or artery into a heart chamber. [Column 6, lines 55-60.] Such a catheter tube simply is not a "**a relatively short, relatively stiff shaft**," as called for in the respective combinations defined by independent claims 1 and 15. As the Swanson '513 patent fails to teach or suggest each and every element of the respective combinations recited in independent claims 1 and 15, applicant respectfully submits that claims 1, 2, 5-11, 15, 17-20 and 25 are patentable thereover and that the rejection under 35 U.S.C. § 102 should be withdrawn.

Turning to the rejection of claims 3, 4, 16 and 21-24 under 35 U.S.C. § 103, applicant respectfully submits that the Lunquist '923 and Abele '311 patents fail to remedy the above-identified teachings in the Swanson '513 patent. For example, the Lundquist '923 and Abele '311 patents are also directed to catheters and, accordingly, would not have led one of skill in the art to substitute a relatively short, relatively stiff

shaft for the catheter tube disclosed in the Swanson '513 patent. As the cited references fail to teach or suggest the respective combinations of elements recited in independent claims 1 and 15, whether viewed alone or in combination, applicant respectfully submits that the rejections of claims 3, 4, 16 and 21-24 under 35 U.S.C. § 103 should be withdrawn.

E. Rejection Based on the Combination of the Edwards '349 and Gough '484 patents

The Edwards '349 patent is directed to a tongue debulking device that includes a plurality of electrodes 12 which may be advanced into tissue and an electrode supporting catheter 14. The Edwards '349 patent discloses that the electrodes 12 may include a central lumen for the **delivery of fluid to the tissue**. [Column 4, lines 55-63.] As such, and in contrast to the combinations respectively defined by independent claims 1 and 15, the Edwards '349 patent does not teach or suggest "an **inflatable**, energy transmitting lesion formation element associated with the distal portion of the shaft **that allows substantially no liquid perfusion therethrough**."

The Gough '484 patent, which discloses various multiple antenna ablation devices that are configured to deliver fluid to tissue, fails to remedy the above-identified deficiencies in the Edwards '349 patent. More specifically, the Gough '484 patent discloses the use of a fluid delivery member 23 "that is **sufficiently porous to permit the passage of fluid**" as well as an expandable member 29 that may be used in combination with the fluid delivery member. [Column 6, lines 34-36; and column 6, line 58 to column 7, line 30.] As such, the Gough '484 patent would not have suggested modifications to the device disclosed in the Edwards '349 patent which would have resulted in the claimed combinations.

As the Edwards '349 and Gough '484 patents fail to teach or suggest the respective combinations of elements recited in independent claims 1 and 15, whether viewed alone or in combination, applicant respectfully submits that the rejection of claims 1-5, 11-17 and 25-28 under 35 U.S.C. § 103 should be withdrawn.

IV. REJECTION OF CLAIM 33 UNDER 35 U.S.C. § 102

A. The Rejection

Claim 33 has been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,183,463 to Debbas (the Debbas '463 patent). The rejection under 35 U.S.C. § 102 is respectfully traversed with respect to the claim as amended above. Reconsideration thereof is respectfully requested.

B. Discussion

Independent claim 33 calls for a combination of elements comprising "a hollow needle" and "a therapeutic assembly, located within the hollow needle and movable relative thereto, including a relatively short shaft defining a distal portion and a proximal portion and ***an inflatable, energy transmitting therapeutic element*** associated with the distal portion of the shaft." The Debbas '463 patent, which discloses various devices for locating a breast mass, fails to teach or suggest such a combination. For example, although the devices disclosed therein include balloons, the balloons do not transmit energy.

As the Debbas '463 patent fails to teach or suggest each and every element of the combination recited in independent claim 33, applicant respectfully submits that claim 33 is patentable thereover and that the rejection under 35 U.S.C. § 102 should be withdrawn.

V. NEWLY PRESENTED CLAIMS 36-48

Newly presented 36-38 depend from independent claim 33 and are patentable for at least the same reasons as independent claim 33.

New presented independent claim 39 calls for a combination of elements comprising "a surgical probe including a relatively short shaft defining a distal portion and a proximal portion and an inflatable, energy transmitting therapeutic element associated with the distal portion of the shaft" and "a cooling fluid source operably connected to the inflatable, energy transmitting therapeutic element and adapted to maintain pressure within the inflatable therapeutic element at a predetermined level." Applicant respectfully submits that the references of record fail to teach or suggest such a combination and that claims 39-48 are patentable thereover.

VI. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

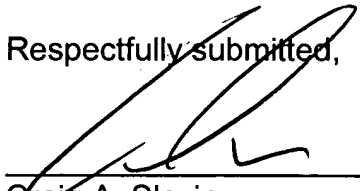
If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

12/7/02
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Respectfully submitted,



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**VERSION OF AMENDMENTS TO APPLICATION WITH
MARKINGS TO SHOW CHANGES MADE**

Claims 1, 5, 6, 9-13, 15, 17-19, 21, 24-27 and 33 have been amended as follows:

1. (Amended) A surgical probe, comprising:
a relatively short, relatively stiff shaft defining a distal portion and a proximal portion; and
an inflatable, energy transmitting lesion formation [therapeutic] element associated with the distal portion of the shaft that allows substantially no liquid perfusion therethrough.

5. (Amended) A surgical probe as claimed in claim 1, wherein at least a portion of the inflatable, energy transmitting lesion formation [therapeutic] element comprises micropores.

6. (Amended) A surgical probe as claimed in claim 1, wherein the inflatable, energy transmitting lesion formation [therapeutic] element includes a distally facing energy transmission region.

9. (Amended) A surgical probe as claimed in claim 6, wherein the inflatable, energy transmitting lesion formation [therapeutic] element includes a proximally facing non-conductive region.

10. (Amended) A surgical probe as claimed in claim 1, wherein the inflatable, energy transmitting lesion formation [therapeutic] element includes an energy transmission region and a non-conductive region and at least one of the energy transmission region and the non-conductive region define a color that visually distinguishes it from the other of the energy transmission region and the non-conductive region.

11. (Amended) A surgical probe as claimed in claim 1, wherein the inflatable, energy transmitting lesion formation [therapeutic] element is mounted on the distal portion of the shaft.

12. (Amended) A surgical probe as claimed in claim 1, wherein the shaft defines a distal end, the surgical probe further comprising:

a needle slidably mounted within the shaft and movable relative to the shaft such that a distal portion of the needle extends outwardly from the distal end of the shaft, the inflatable, energy transmitting lesion formation [therapeutic] element being mounted on the distal portion of the needle.

13. (Amended) A surgical probe as claimed in claim 12, wherein the needle comprises a plurality of needles and the inflatable, energy transmitting lesion formation [therapeutic] element comprises a plurality of inflatable, energy transmitting lesion formation [therapeutic] elements respectively mounted on the plurality of needles.

15. (Amended) A surgical probe system, comprising:

a surgical probe including a relatively short, relatively stiff shaft defining a distal portion and a proximal portion and an inflatable, energy transmitting lesion formation [therapeutic] element associated with the distal portion of the shaft that allows substantially no liquid perfusion therethrough; and

a fluid source operably connected to the inflatable therapeutic element and adapted to maintain pressure within the inflatable therapeutic element at a predetermined level.

17. (Amended) A surgical probe system as claimed in claim 15, wherein at least a portion of the inflatable, energy transmitting lesion formation [therapeutic] element comprises micropores.

18. (Amended) A surgical probe system as claimed in claim 15, wherein the inflatable, energy transmitting lesion formation [therapeutic] element includes a distally facing energy transmission region.

19. (Amended) A surgical probe system as claimed in claim [14] 15, wherein the distally facing energy transmission region is annularly shaped.

21. (Amended) A surgical probe system as claimed in claim 19, further comprising a pressure sensor adapted to determine the pressure within the inflatable, energy transmitting lesion formation [therapeutic] element.

24. (Amended) A surgical probe system as claimed in claim 19, wherein the fluid source continuously infuses fluid to and ventilates fluid from the inflatable, energy transmitting lesion formation [therapeutic] element.

25. (Amended) A surgical probe system as claimed in claim 15, wherein the inflatable, energy transmitting lesion formation [therapeutic] element is mounted on the distal portion of the shaft.

26. (Amended) A surgical probe system as claimed in claim 15, wherein the shaft defines a distal end, the surgical probe further comprising:

a needle slidably mounted within the shaft and movable relative to the shaft such that a distal portion of the needle extends outwardly from the distal end of the shaft, the inflatable, energy transmitting lesion formation [therapeutic] element being mounted on the distal portion of the needle.

27. (Amended) A surgical probe system as claimed in claim 26, wherein the needle comprises a plurality of needles and the inflatable, energy transmitting lesion formation [therapeutic] element comprises a plurality of inflatable, energy transmitting lesion formation [therapeutic] elements respectively mounted on the plurality of needles.

33. (Amended) A surgical probe, comprising:
- a hollow needle; and
 - a therapeutic assembly, located within the hollow needle and movable relative thereto, including a relatively short shaft defining a distal portion and a proximal portion and an inflatable, energy transmitting therapeutic element associated with the distal portion of the shaft.